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STEVEN F WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
D 377 AP6D
ABBOTT PARK, IL 60064-6050

EXAMINER
OLSEN, KAJ K

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Please find below and/or attached an Office communication concerning this application or proceeding.

ML

Office Action Summary	Application No. 09/529,617	Applicant(s) FORROW ET AL.	
	Examiner Kaj Olsen	Art Unit 1744	

-- The MAILING DATE of this communication app ars on the cover she t with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☒ Claim(s) 7 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: On pages 20 and 28, applicant incorporates figures into the body of the specification. These figures in the disclosure should be appropriately provided with the other figures outside of the body of the specification.

Appropriate correction is required.

Claim Objections

Claim 7 is objected to because of the following informalities: The examiner cannot tell if claim 7 is dependent off of claim 6 or claim 5. The provided amendment sheet of the claims in this national stage application is of poor quality and the dependency of claim 7 is smudged. For the purpose of applying prior art, the examiner is interpreting claim 7 as being dependent off of claim 6, but clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geng et al, "Amperometric biosensors based on dehydrogenase/NAD and heterocyclic quinones", Biosensors and Bioelectronics, 11, 1996, pp. 1267-1275 (hereafter "Geng") in view of MacFarlane et al (USP 5,212,622) and Carter et al (USP 5,628,890).

Geng discloses an electrode-based sensor for the detection of glucose in an aqueous sample. The sensor comprises an electrode having a nicotinamide cofactor dependent enzyme glucose dehydrogenase (GDH), a cofactor of nicotinamide adenine dinucleotide (NAD/NADH), and a mediator of 1,10-phenanthroline quinone that reads on one of the claimed formulae (see introduction and section titled "Chemical and materials", pp. 1267-68). Although Geng does not explicitly identify formulating the active electrode filler and binder ingredients, MacFarlane teaches that it is conventional in the art to incorporate filler and binder materials in the electrode in order to prevent the ionic and electroactive material loss (col. 1, lines 53-61 and col. 2, line 61 through col. 4, line 11). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of MacFarlane for the sensor of Geng in order to increase sensor stability and thereby improve sensor performance. The monotonic performance of the sensor over the claimed concentration range would appear to be function of the increased stability of the sensor that was rendered obvious by the teaching of MacFarlane. In

addition, Geng indicates the sensor can be made monotonic over the claimed range (see solid squares in fig. 10 and the summary on p. 1274).

With respect to the limitations drawn to the use of the various supports, conductive tracks with reference and counter electrodes, all these specified elements are conventional aspects of electrode strip construction. Carter shows a protocol for constructing strip sensors and provides a sensor where the location of the sample delivery can be controlled making the sensor easy for the user to manipulate (see fig. 1 and the associated discussion therein). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Carter for the sensor of Geng and MacFarlane because the protocol of Carter is conventional in the art and provides a sensor that is easy for the user to manipulate. Geng utilizes 200 mV.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batchelor et al, "Amperometric assay for the ketone body 3-hydroxybutyrate", Anal. Chim. Acta, 221, 1989, pp. 289-294 (hereafter "Batchelor") in view of Geng, MacFarlane, and Carter.

Batchelor teaches an electrode-based sensor for the detection of 3-hydroxybutyrate (3-OHB) that utilizes 3-hydroxybutyrate dehydrogenase (HBDH), an NAD/NADH cofactor, and a quinone mediator (see fig. 1). Said quinone mediator does not read on either of the claimed formulae. The previously discussed Geng teaches that phenanthroline quinones, which do read on the claimed formulae, have low redox potentials and can oxidize NADH efficiently (see section titled "cyclic voltammetry of heterocyclic quinones", p. 1269). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the

teaching of Geng for the sensor of Batchelor because the identified mediator of Geng can readily oxidize NADH at low redox potentials thereby improving sensor performance.

With respect to the limitations drawn to the use of fillers, binders, and various strip components, MacFarlane teaches that it is conventional in the art to incorporate filler and binder materials in the electrode in order to prevent the ionic and electroactive material loss (col. 1, lines 53-61 and col. 2, line 61 through col. 4, line 11). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of MacFarlane for the sensor of Batchelor and Geng in order to increase sensor stability and thereby improve sensor performance. The monotonic performance of the sensor over the claimed concentration range would appear to be function of the increased stability of the sensor that was rendered obvious by the teaching of MacFarlane. In addition, Batchelor shows a monotonic and substantially linear response from 1-8 mM of analyte (fig. 3).

With respect to the limitations drawn to the use of the various supports, conductive tracks with reference and counter electrodes, all these specified elements are conventional aspects of electrode strip construction. Carter shows a protocol for constructing strip sensors and provides a sensor where the location of the sample delivery can be controlled making the sensor easy for the user to manipulate (see fig. 1 and the associated discussion therein). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Carter for the sensor of Batchelor, Geng, and MacFarlane because the protocol of Carter is conventional in the art and provides a sensor that is easy for the user to manipulate.

With respect to the use of GDH, Geng already disclosed the use of GDH for amperometric biosensors (see discussion above) and Geng teaches the use of 200 mV for phenanthroline quinones.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geng, MacFarlane, and Carter as applied to claim2 above, and further in view of Batchelor.

The references set forth the limitations of the claim, but did not explicitly identify the use of HBDH as the cofactor-dependent enzyme. Geng recognizes the utility of the described glucose sensor for other sensing applications utilizing NAD(P) cofactors (see title and introduction). Batchelor teaches an analogous sensor which utilizes the enzyme 3-hydroxybutyrate dehydrogenase which is thereby capable of measuring 3-hydroxybutyrate (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Geng in order to extend the utility of the sensor of Geng to additional compounds such as 3-hydroxybutyrate.

Claims 5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batchelor in view of Geng.

With respect to these claims (those limitations not covered above) Batchelor demonstrates very clearly in fig 1 how the various components of the sensor interact each other. In particular, fig. 1 shows how the dehydrogenase oxidizes the analyte in the presences of NAD. The NAD is reduced to NADH and subsequently reoxidized by the quinone mediator. A potential applied to the electrode causes the mediator to reoxidize where the resultant current is monotonically related to the concentration of analyte (i.e. 2 electrons for every analyte molecule (see also fig. 3)). Said quinone mediator does not read on either of the claimed formulae. The

previously discussed Geng teaches that phenanthroline quinones, which do read on the claimed formulae, have low redox potentials and can oxidize NADH efficiently (see section titled "cyclic voltammetry of heterocyclic quinones", p. 1269). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Geng for the sensor of Batchelor because the identified mediator of Geng can readily oxidize NADH at low redox potentials thereby improving sensor performance. Geng teaches the use of 200 mV for phenanthroline quinones and the use of GDH (see discussion above).

Claims 5 and 8-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Geng as evidence by, or in view of Batchelor.

With respect to these claims (those limitations not already discussed above) Geng set forth the various components of the sensor and teaches how the various components interact to provide the sensor. However, Geng doesn't set forth the various claimed steps of oxidation and reduction for the sensor as clearly as Batchelor did (see discussion above). The diagram shown by Batchelor is the same protocol utilized for Geng with the substitution of 3-OHB and HBDH in the diagram for glucose and GDH respectively. In this instance, Batchelor is being utilized solely to evidence what Geng already teaches (just not as pictorially as Batchelor does). With respect to claim 10, Geng recognizes the utility of the described glucose sensor for other sensing applications utilizing NAD(P) cofactors (see title and introduction). Batchelor teaches an analogous sensor which utilizes the enzyme 3-hydroxybutyrate dehydrogenase which is thereby capable of measuring 3-hydroxybutyrate (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of

Batchelor for the sensor of Geng in order to extend the utility of the sensor of Geng to additional compounds such as 3-hydroxybutyrate.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geng and Batchelor (or alternately, Batchelor in view of Geng) as applied to claim 5 above, and further in view of MacFarlane.

The references set forth all the limitations of the claims, but did not explicitly teach the use of binders and fillers for the electrode surface. MacFarlane teaches that it is conventional in the art to incorporate filler and binder materials in the electrode in order to prevent the ionic and electroactive material loss (col. 1, lines 53-61 and col. 2, line 61 through col. 4, line 11). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of MacFarlane for the sensors of Batchelor and Geng in order to increase sensor stability and thereby improve sensor performance. The monotonic performance and linearity of the sensor over the claimed concentrations would appear to be function of the increased stability of the sensor that was rendered obvious by the teaching of MacFarlane. In addition, both sensors set forth monotonic and linear sensor performance (see discussions above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 8:00 AM-5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen, Ph.D.

Patent Examiner

AU 1744

ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700